

PCB INSPECTION REPORT

FACILITY

Reliable Biopharmaceutical Corporation
1945 Walton Road
Overland, MO 63114
(314) 429-7700

Date: December 22, 2008
Inspection No. 122208411701
Docket No. 07-09-T-818
FRS. 110000441228

INTRODUCTION

County: St. Louis

This facility was selected under the Regional Neutral Scheme as a random selection. The reason for the inspection was to determine compliance with PCB regulations, as codified in 40 CFR, Part 761.

SUMMARY OF OBSERVATIONS

No apparent deviations from PCB regulations were observed during this inspection.

No samples, documents, or photographs were taken.

HISTORY OF BUSINESS

Reliable Biopharmaceutical Corporation conducts research and development of pharmaceuticals, purifies chemicals for the pharmaceutical industry, and is a contract manufacturer of pharmaceuticals. The facility has been in business for approximately 23 years and at the present location for approximately 10 years. The facility consists of two buildings covering approximately 30,000 square feet. There are approximately 60 employees.

The president of the company is Mr. Michael Zaleski. His address is the same as the facility's.

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES

Mr. Charles Wisdom, environmental health and safety manager, was interviewed. Mr. Wisdom signed and received copies of all inspection documents, provided information about the facility, accompanied me during the physical inspection, and was present during the closing discussion.

Mr. Mark Stinnis, maintenance manager, was interviewed. Mr. Stinnis provided information about the facility.

INSPECTION

On December 22, 2008, I, David Giarratano, presented my credentials to Mr. Charles Wisdom, environmental health and safety manager. I advised Mr. Wisdom that Reliable Biopharmaceutical Corporation had been selected for inspection under the Regional Neutral Scheme as a random selection. I issued the Notice of Inspection and Confidentiality Notice to Mr. Wisdom, who signed and received copies of both. Mr. Wisdom stated there would be no claim of confidentiality.

I asked Mr. Wisdom if Reliable Biopharmaceutical Corporation owned any transformers or capacitors. He said the transformers providing service to the facility were owned by the company.

He asked Mr. Mark Stinnis, maintenance manager, to join us. Mr. Stinnis corroborated that the transformers were owned by the company. He added that the main transformer was installed about six years ago when a building expansion occurred. He said there were no capacitors in their

JAN 08 2009

PCB INSPECTION REPORT
Reliable Biopharmaceutical Corporation
Overland, MO
December 22, 2008
Page Two

electrical system. He added that all of the electrical equipment inside the facility was dry-type. Mr. Wisdom and I left the office for the physical inspection.

We began the inspection by going through the laboratory, production, and warehouse areas. I saw no oil-filled electrical equipment in these areas. We continued to the main electrical room. There were dry-type transformers, switches, and circuit breakers in this location.

We then went outside to look at the main transformer. On the north side of the building was a platform-mount transformer. There was a label stating it was filled with non-PCB fluid dated November 2000. It did not appear to be leaking.


This completed the physical inspection. We went back to the office for the closing conference.

CLOSING CONFERENCE


The closing conference was with Mr. Charles Wisdom, environmental health and safety manager.

I told Mr. Wisdom I observed no apparent deviations from PCB regulations during the inspection. Mr. Wisdom signed and received copies of the Receipt for Samples, Declaration of CBI, and Summary of Observations.

SUBMITTED BY:


David J. Giarratano, Chief
Special Facilities Unit
Compliance and Enforcement Section
Hazardous Waste Program
December 24, 2008

APPROVED BY:


Kathy S. Flippin, Chief
Compliance and Enforcement Section
Hazardous Waste Program

KSF:dgm

ATTACHMENTS

1. Notice of Inspection
2. Summary of Observations
3. Receipt for Samples
4. Confidentiality Notice
5. Declaration of CBI
6. ICDS



United States Environmental Protection Agency
Washington, D.C. 20460
Toxic Substances Control Act
NOTICE OF INSPECTION

Form Approved
OMB No. 2070-0007

The public reporting burden for this collection of information is estimated to average 5 minutes per response. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the needed data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Chief, Information Policy Branch (PM-223), US Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked ATTENTION: Desk Officer for EPA.

1. Investigation Identification			2. Time	3. Firm Name
Date 12/22/08	Inspector No. 4117	Daily Seq. No. 01	12:50	Reliable Biopharmaceutical Corp
4. Inspector Address MDNR/HWP P.O. Box 176 Jefferson City, MO 65102				5. Firm Address 1945 Watson Rd St. Louis Mo

REASON FOR INSPECTION

Under the authority of Section 11 of the Toxic Substances Control Act:

☒ For the purpose of inspecting (including taking samples, photographs, statements, and other inspection activities) an establishment, facility, or other premises in which chemical substances or mixtures or articles containing same are manufactured, processed or stored, or held before or after their distribution in commerce (including records, files, papers, processes, controls, and facilities) and any conveyance being used to transport chemical substances, mixtures, or articles containing same in connection with their distribution in commerce (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of the Act applicable to the chemical substances, mixtures, or articles within or associated with such premises or conveyance have been complied with.

☐ In addition, this inspection extends to (Check appropriate blocks):

☐ A. Financial data

☐ D. Personnel data

☐ B. Sales data

☐ E. Research data

☐ C. Pricing data

The nature and extent of inspection of such data specified in A through E above is as follows:

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Inspector Signature 		Recipient Signature 	
Name David Giannatano		Name Charles Wisdom	
Title Env. Spec.	Date Signed 12/22/08	Title EHS Mgr	Date Signed 12/22/08

Attachment 1

U.S. ENVIRONMENTAL PROTECTION AGENCY

TSCA INSPECTION

SUMMARY OF OBSERVATIONS

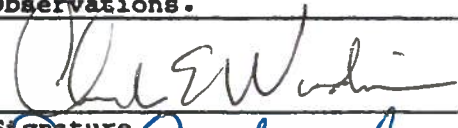

Name and Address of Inspector(s) Reliable David Giarratano MDNR/HWP P.O. Box 176 Jefferson City, MO 65102		Name and Address of Facility Reliable Biopharmaceutical Corp 1945 Walton Road Overland MO 63114	
Name of Individual to Whom Notice Given Charles Wisdom		Chief Executive Officer of Firm Michael Zaleski	
Title EHS Mgr	Date 12/22/8	Title President Address 1945 Walton Rd Overland MO 63114	

The following possible deviations from the requirements of the Toxic Substances Control Act and regulations promulgated thereto were observed during this inspection:

no apparent deviations from PCB regulations
were observed during this inspection

This Summary of Observations is provided to bring to your attention those areas of concern at the earliest possible time. It is not intended to be a complete list of deviations from the requirements of the Toxic Substances Control Act and regulations thereto, but rather a list of those conditions of immediate concern and/or those readily apparent. If you have any questions regarding this summary, please contact the Chemical Risk Information Branch at 913/551-7020.

The undersigned acknowledges having received and read a copy of this TSCA Summary of Observations.

Signature 		EHS Mgr		12/22/8
Signature of Inspector 		Title of Inspector Env Spec		Date 12/22/8

Distribution: White - Regional Office Copy
Yellow- Facility Copy



US ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

TOXIC SUBSTANCES CONTROL ACT

RECEIPT FOR SAMPLES AND DOCUMENTS

1. INVESTIGATION IDENTIFICATION			2. COMPANY NAME
DATE 12/22/08	INSPECTION NO. 4117	DAILY SEQ. NO. 01	Reliable Biopharmaceutical Corp
3. INSPECTOR ADDRESS MDNR/HWP P.O. Box 176 Jefferson City, MO 65102			4. COMPANY ADDRESS 1945 Walton Rd Overland Mo 63144

For internal EPA use. Copies of this form may be provided to recipient as acknowledgement of the documents and samples of chemical substances and/or mixtures described below collected in connection with the administration and enforcement of the Toxic Substances Control Act.

RECEIPT OF DOCUMENT(S) AND/OR SAMPLE(S) DESCRIBED IS HEREBY ACKNOWLEDGED:

NO.	DESCRIPTION
	no samples, documents or photographs were taken

OPTIONAL:

DUPLICATE OR SPLIT SAMPLES: REQUESTED AND PROVIDED ☐

NOT REQUESTED ☐

INSPECTOR SIGNATURE 		CLAIMANT SIGNATURE 	
NAME David Giarrabino		NAME Charles Witsdon	
TITLE Env. Spec.	DATE SIGNED 12/22/8	TITLE EHS Mgr	DATE SIGNED 12/22/8

Attachment 3

INSPECTOR'S COPY



United States Environmental Protection Agency

Washington, D.C. 20460

Toxic Substances Control Act

Form Approved

OMB No. 2070-0007

Approval Expires 10-31-92

TSCA INSPECTION CONFIDENTIALITY NOTICE

The public reporting burden for this collection of information is estimated to average 5 minutes per response. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the needed data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to the Chief, Information Policy Branch (PM-223), US Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked ATTENTION: Desk Officer for EPA.

1. Investigation Identification			2. Firm Name
Date 12/22/08	Inspector No. 4117	Daily Seq. No. 01	Reliable Biopharmaceutical Corp
3. Inspector Name David Giarratano			4. Firm Address 1945 Walton Rd Overland Mo 63114
5. Inspector Address MDNR/HWP P.O. Box 176 Jefferson City, MO 65102			6. Chief Executive Officer Name Michael Zaleski
			7. Title President

TO ASSERT A CONFIDENTIAL BUSINESS INFORMATION CLAIM

It is possible that EPA will receive public requests for release of the information obtained during inspection of the facility above. Such requests will be handled by EPA in accordance with provisions of the Freedom of Information Act (FOIA), 5 USC 552; EPA regulations issued thereunder, 40 CFR Part 2; and the Toxic Substances Control Act (TSCA), Section 14. EPA is required to make inspection data available in response to FOIA requests unless the Administrator of the Agency determines that the data contain information entitled to confidential treatment or may be withheld from release under other exceptions of FOIA.

Any or all the information collected by EPA during the inspection may be claimed confidential if it relates to trade secrets or commercial or financial matters that you consider to be confidential business information. If you assert a CBI claim, EPA will disclose the information only to the extent, and by means of the procedures set forth in the regulations (cited above) governing EPA's treatment of confidential business information. Among other things, the regulations require that EPA notify you in advance of publicly disclosing any information you have claimed as confidential business information.

A confidential business information (CBI) claim may be asserted at any time. You may assert a CBI claim prior to, during, or after the information is collected. The declaration form was developed by the Agency to assist you in asserting a CBI claim. If it is more convenient for you to assert a CBI claim on your own stationery or by marking the individual documents or samples "TSCA confidential business information," it is not necessary for you to use this form. The inspector will be glad to answer any questions you may have regarding the Agency's CBI procedures.

While you may claim any collected information or sample as confidential business information, such claims are unlikely to be upheld if they are challenged unless the information meets the following criteria:

1. Your company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.

2. The information is not, and has not been, reasonably obtainable without your company's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on showing of special need in a judicial or quasi-judicial proceeding).
3. The information is not publicly available elsewhere.
4. Disclosure of the information would cause substantial harm to your company's competitive position.

At the completion of the inspection, you will be given a receipt for all documents, samples, and other materials collected. At that time, you may make claims that some or all of the information is confidential business information.

If you are not authorized by your company to assert a CBI claim, this notice will be sent by certified mail, along with the receipt for documents, samples, and other materials to the Chief Executive Officer of your firm within 2 days of this date. The Chief Executive Officer must return a statement specifying any information which should receive confidential treatment.

The statement from the Chief Executive Officer should be addressed to:

TSCA FOIA Officer
EPA Region VII
901 N. 5th Street
Kansas City, KS 66101

and mailed by registered, return-receipt requested mail within 7 calendar days of receipt of the Notice. Claims may be made any time after the inspection, but inspection data will not be entered into the special security system for TSCA confidential business information until an official confidentiality claim is made. The data will be handled under the agency's routine security system unless and until a claim is made.

TO BE COMPLETED BY FACILITY OFFICIAL RECEIVING THIS NOTICE:

I have received and read the notice.

If there is no one on the premises of the facility who is authorized to make business confidentiality claims for the firm, a copy of this Notice and other inspection materials will be sent to the company's chief executive officer. If there is another company official who should also receive this information, please designate below.

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature Charles E. Wisdom	Name
Name Charles Wisdom	Title
Title EHS Mgr	Date Signed 12/22/08
Address	

Attachment 4



US ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

TOXIC SUBSTANCES CONTROL ACT

DECLARATION OF CONFIDENTIAL BUSINESS INFORMATION

1. INVESTIGATION IDENTIFICATION			2. COMPANY NAME
DATE 12/22/08	INSPECTION NO. 4117	DAILY SEQ. NO. 01	Reliable Biopharmaceutical Corp
3. INSPECTOR ADDRESS MDNR/HWP P.O.Box 176 Jefferson City, MO 65102			4. COMPANY ADDRESS 1945 Walton Rd Overland Mo 63114

For internal EPA use. Copies of this form may be provided to recipient as acknowledgement of TSCA Confidential documents described below collected in connection with the administration and enforcement of the Toxic Substances Control Act.

INFORMATION DESIGNATED AS CONFIDENTIAL BUSINESS INFORMATION

NO.	DESCRIPTION
	none declared

INSPECTOR SIGNATURE 		CLAIMANT SIGNATURE 	
NAME David Giarratano		NAME Charles Wisdom	
TITLE Env. Spec.	DATE SIGNED 12/22/8	TITLE Env. Spec.	DATE SIGNED 12/22/8

Attachment 5